

## **REMARKS**

Claims 1 and 3-12 are pending. Claims 6-11 are withdrawn as nonelected.

At page 1 of the Action, the Examiner lists claim 12 as withdrawn. Applicants believe this is incorrect because (1) page 2 of the Action states that claim 12 is under examination, and (2) the Examiner rejected claim 12 in the April 9, 2009 Action. Applicants respectfully requests claim 12 status correction.

### **CLAIM REJECTIONS UNDER 35 U.S.C. §112**

Claims 1, 3-5, and 12 are rejected under 35 U.S.C. §112 ¶2 as indefinite.

Independent claims 1 and 12 are amended to overcome the rejection. The amendment is supported at least at p. 4 line 22 and p. 4 line 33 to p. 5 line 2 and thus introduces no new matter. Applicants respectfully request the rejection be withdrawn.

### **CLAIM REJECTIONS UNDER 35 U.S.C. §103**

Claims 1, 3-5, and 12 are rejected under 35 U.S.C. §103(a) as obvious over Klopfenstein (EP 0354027), Parham (US 4596770), Dunn (EP 0950403), and Mitchell (WO 94/13777), in view of Gosnell (US 2002/0086278) and Ward (US 5403721).

Applicants respectfully assert that the Examiner has not fully considered their July 7, 2009 arguments.

As one example, at p. 8 of the Action, the Examiner acknowledges accuracy of Applicants' position that Klopfenstein teach a cleaning solvent, and not a solvent that extends the stability over time of chromogenic substrates used in biological assays. Thus, the Examiner's further statement

...however, [Klopfenstein] teach[es] that the components of the instant composition are known to be present in composition together, are known to have various additives, and are known to comprise water, if desired

ignores each of:

(1) the claim limitation that Applicants' composition is a chromogenic substrate used in a biological assay. The amended claims recite the solubilizing agent at a concentration sufficient to keep substrate activity for more than 6 months in solution at 4°C. Klopfenstein would not render obvious such a biological activity-based parameter.

(2) Applicants' assertion that a person skilled in the art would not look to a teaching of solvents to clean, e.g., printing ink, machine tools, carpets, upholstery, and electronics manufacture (Klopfenstein col. 2, line 16 to col.13 line 11), analogous to solvents that stabilize compositions to detect a biological process. The purposes are different: cleaning stains, debris, etc. in Klopfenstein, versus to stabilizing a substrate in a biological assay. The compositions are different: Klopfenstein does not require the solubilizing agent to be present in a concentration to stabilize activity. The person skilled in the art is different: a non-biological scientist skilled in solvents that may be "flushed with water into municipal sewer systems... and [that] exhibit superior solvency characteristics and may be used in may cleaning, de-

greasing and cutting applications" (Klopfenstein col. 1 lines 11-29), versus a biological scientist skilled in detecting expression or non-expression of a lacZ gene.

(3) Klopfenstein's specific disclosure of a non-aqueous composition, in fact, that water is not desirable because it significantly decreases performance ("it is not desirable to include water in the compositions as fabricated because of a significant decrease in performance" and is not required for stability ("The compositions of the present invention are preferably essentially non-aqueous, because these compositions are stable liquids in the absence of added water") Klopfenstein col. 6 ¶3. This is in contrast to Applicants' disclosure of a dipolar microemulsion solvent:

A micro emulsion is a thermodynamically stable dispersion of one liquid phase into another, stabilized by an interfacial film of surfactant. This dispersion may be either oil-in-water or water-in-oil. (Page 5, lines 13-16)

As another example, at pp. 7-8 of the Action, the Examiner's "Response to Arguments" specifically addresses only Applicants' arguments against Klopfenstein. It states:

Applicants also argue that one of skill would not apply 80% cyclic terpene to a colorimetric composition. However, the amounts of terpenes, as taught in the various prior art documents, varies widely and it is taught that one of skill can choose the components and amounts to best suit the desired effect of the organic solvent compound: cell transformation, cleaning solvent, microemulsion with chromogens, etc. Applicants argue that each reference does not specifically teach a microemulsion, however the prior art teaches that emulsion solutions are known to be made with the instant combination of elements.

However, as a person skilled in the art knows, and as Applicants specifically teach, microemulsions differ from emulsions:

Micro emulsions are typically clear solutions, as the droplet diameter is approximately 100 nanometers or less. The interfacial tension between the two phases is extremely low. Emulsions are in contrast unstable, the suspended droplets will eventually agglomerate and the dispersed phase will phase separate. Emulsion droplet sizes are much larger, typically one micron or more, resulting in a cloudy or milky dispersion (p. 5 lines 16-22),

Emulsions, thus, do not provide the same characteristics nor the same properties as Applicants' claimed microemulsion solvent for a chromogenic substrate.

For at least these reasons, Applicants respectfully assert that Klopfenstein, Parham, Dunn and Mitchell, in view of Gosnell and Ward, do not render claims 1, 3-5, and 12 obvious, and request the rejection be withdrawn.

## **CONCLUSION**

The application is believed to be in complete condition for allowance. The Request for Continued Examination fee is being simultaneously paid by electronic funds transfer. No other fees are believed due but, if deemed necessary, the Office is authorized to charge them to Deposit Account 20-0809.

The Examiner is invited to contact Applicants' undersigned representative with questions.

Respectfully submitted,  
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